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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,826	11/26/2003	Edmund Radmacher	16202.970	4787

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EXAMINER

NAGPAUL, JYOTI

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 02/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/721,826

Applicant(s)

RADMACHER ET AL.

Examiner

Jyoti Nagpaul

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Amendment filed on November 18, 2005 has been acknowledged. Claims 1-24 are pending.

#### ***Response to Amendment***

Rejection of Claims 1-20 as being anticipated by Smith (US 637028) has been *maintained* in light of applicant's arguments.

#### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1-23** are rejected under 35 U.S.C. 102(b) as being anticipated by Smith (US 637028).

Smith discloses a centrifuge tube for dispensing urine or serum/ processing biomolecules. The separation device (50) comprises a separation column (142) that has a top side inlet (146) and a bottom side outlet (152) and in which separation material (150) is arranged and a collection vessel (162) for collecting the liquid exiting from the outlet (152), where in the separation column (142) is inserted into the collection vessel (50) and is closed off with a removable cover (44). (See Fig. 22) Smith further teaches the pressure-equalizing connection (154 and according to Figure 22, the pressure-equalizing connection is the space/channel between the collection vessel (162) and separation column (142)) is disposed apart from the separation material

(150). The separation column (142) has an edge flange (149) that is pressed onto the collection vessel (162) by means of the cover (40). (See Fig. 22) Smith discloses the interior of the collection vessel and the separation column has pressure-equalizing connection (154 and according to Figure 22, the pressure-equalizing connection is the space/channel between the collection vessel (162) and separation column (142)), in addition to the outlet (152) from the separation column. According to Figure 22, a pressure-equalizing connection has a port/openings (154) in the upper region of the separation column (142). In Figure 22, the edge flange (149) lies on the upper edge of the collection vessel (50). With regards to Claim 12, it appears that the volume enclosed by the collection vessel (50) beneath the lower end of the outlet (144) of the separation column (142) is at least 1.5 times as large as the free volume of the separation column. Smith teaches different variations of the same embodiment. Smith teaches the use of a filter (140) arranged in the separation column as shown in Figures 20 or 20A. (Col. 17, Lines 28-33). Smith further teaches the separation device (50) is used for processing of tissues or other specimens. Smith teaches, "micro centrifuge tubes is the requirement to filter aqueous samples for clarification, particulate removal and/or sample preparation prior to the liquid being dispensed into the tube for testing." (See Col. 3, Lines 28-32) Smith further teaches, "the new invention addresses these problems with a one-piece design" (See Col. 3, Lines 41-42) Smith teaches micro centrifuge tubes/separation device (50) for storage and **processing** of tissue samples. Smith further teaches, "this would then allow the user to remove the bag from the storage container 162 by disengaging it from the cap 149 and be used for further

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evaluations and/or **testing** as are normal biopsy bags used in histology laboratories.”

(See Col. 18, Lines 40-44) Smith further teaches, “The present invention provides for a threaded cap design that incorporates a pressure responsive diaphragm that increases the sealing effectiveness of the cap when the internal pressures of the container increase during **testing** or storage (i.e.: **centrifugation**, heating and freezing).” (See Col. 3, Lines 65-66 to Col. 4, Lines 1-4) Smith further teaches centrifuging a fluid in the separation device (50) to separate a material from the fluid while permitting the pressure-equalizing connection to equalize pressures between the interior of the collection vessel and the separation column.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. **Claim 24** is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith in view of Lewis.

Please refer to Smith's teachings above.

Smith does teach micro centrifuge tubes/separation device (50) for storage and processing of **tissue** samples or other specimens. (See Col. 18, Lines 23-25)

Smith fails to explicitly teach the fluid comprises a bodily liquid and wherein centrifuging comprises separating nucleic acids from the bodily liquid.

Lewis teaches a centrifuge device for separating nucleic acids from bodily liquid. (Col. 2, Lines 21-24)

It would have been obvious to one of the ordinary skill in this art at the time the invention to provide the device of Smith such that the separation device of Smith be used for separating nucleic acids from bodily liquid in order to analyze a nucleic acid sample to further optimize the use of the device.

### ***Response to Arguments***

With respect to Claims 1-20, applicant's arguments filed on November 18, 2005 have been fully considered but they are not persuasive. Applicant argues that no

separation takes place in the device of Smith. However, this is a method limitation and not a structural limitation. A method limitation does not add patentable weight in a claim to the device. It is also noted that Smith does teach separation as described in his teachings above. For the newly filed method claims, the limitation with respect to centrifuging has been addressed.

### ***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jyoti Nagpaul whose telephone number is 571-272-1273. The examiner can normally be reached on Monday thru Friday (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JN

  
Jill Warden  
Supervisory Patent Examiner  
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